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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,650	05/09/2006	David B. Weiner	UPAPO020-100	2255
34137	7590	05/05/2009	EXAMINER	
Pepper Hamilton LLP 400 Berwyn Park 899 Cassatt Road Berwyn, PA 19312-1183			SHEN, WU CHENG WINSTON	
			ART UNIT	PAPER NUMBER
			1632	
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			05/05/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/560,650

Applicant(s)

WEINER ET AL.

Examiner

WU-CHENG Winston SHEN

Art Unit

1632

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 14-17, 19, 21-23, 38 and 54-77 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1 and 77 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

The claim amendments filed on 01/29/2009 has been received and entered. Claim 77 is newly added. Claims 1, 21-23, 61-63, 73, and 74 have been amended. Claims 1, 14-17, 19, 21-23, 38 and 54-77 are pending. *The following Elections/restrictions are necessitated by claim amendments filed on 01/29/2009.*

Election/Restrictions

As documented on page 2 of the office action mailed on 07/29/2008, Applicant's election of Group III, claims 1-6, 8, 9, 11, 14-17, 19-23, 29, 38, and 54 (each in part), drawn to an isolated nucleic acid molecule comprising a nucleic acid sequence consisting of: a nucleic acid sequence that encodes a fusion protein that consists of a *non-IgE protein sequences fused to an IgE signal peptide* that is from the same species as the non-IgE protein, a composition comprises the nucleic acid, a pharmaceutical composition comprises the nucleic acid, an recombinant vaccine comprises the nucleic acid, in the reply filed on 04/29/2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

(I) Claim 1 filed on 01/29/2009 has been amended to read as follows: An isolated nucleic acid molecule comprising a nucleic acid sequence selected from the group consisting of: a nucleic acid sequence that encodes a fusion protein that consists of a *non-IgE protein sequences linked to an IgE signal peptide* that is from the same species as the non-IgE protein; and a nucleic acid sequence that encodes a fusion protein that consists of a *non-IgE protein sequences linked to*

an IgE signal peptide, wherein the non-IgE protein is an immunomodulating protein selected from the group consisting of cytokines, chemokines, cellular death receptors, cellular adhesion molecules, cellular growth factors, cellular growth factor receptors, protein kinases and enzymes or functional fragment thereof.

(II) Newly added claim 77 filed on 01/29/2009 read as follows: The isolated nucleic acid molecule of claim 1 wherein the immunomodulating protein is selected from the group consisting of wherein the non-IgE protein is an immunomodulating protein selected from the group consisting of an enzyme, functional fragment thereof, IL-15, CD40L, TRAIL; TRAILrecDRC5, TRAIL-R2, TRAIL-R3, TRAIL-R4, RANK, RANK LIGAND, OX40, OX40 LIGAND, NKG2D, F461811 or MICA, MICB, NKG2A, NKG2B, NKG2C, NKG2E, NKG2F, CD30, CD153 (CD30L), Fos, cjun, Sp-1, Apl, Ap-2, p38, p65Rel, MyD88, IRAK, TRAF6, Ikb, NIK, SAP K, SAP1, JNK2, JNK1B2, JNK1B1, JNK2B2, JNK2B1, JNK1A2, JNK2A1, JNK3A1, JNK3A2, NF-kappa-B2, p49 splice form, NF-kappa-B2, p100 splice form, NF-kappa-B2, p 105 splice form, NF-kappa-B 50K chain precursor, NFkB p50, human IL-1 a, human IL-2, human IL-4, murine IL-4, human IL-5, human IL-10, human IL-15, human IL-18, human TNF-a, human TNF-P, human interleukin 12, MadCAM-1, NGF IL- 7, VEGF, TNF-R, Fas, CD40L, IL-4, CSF, G-CSF, GM-CSF, M-CSF, LFA-3, ICAM-3, ICAM- 2, ICAM-1, PECAM, P150.95, Mac-1, LFA-1, CD34, RANTES, IL-8, MIP-1a, E-selecton, CD2, MCP-1, L-selecton, P-selecton, FLT, Apo-1, Fas, TNFR-1, p55, WSL-1, DR3, TRAMP, Apo-3, AIR, LARD, NGRF, DR4 (TRAIL), DR5, KILLER, TRAIL-R2, TRICK2, DR6, ICE, VLA-1, and CD86 (B7.2).

1. (I) This application as amended contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows: (i) cytokines, (ii) chemokines, (iii) cellular death receptors, (iv) cellular adhesion molecules, (v) cellular growth factors (vi) cellular growth factor receptors, (vii) protein kinases, (viii) enzymes, and (ix) functional fragment thereof an enzyme (claim 1). Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. These species are patentably distinct because they are different proteins encoded by different genes and have different biological functions. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

(II) This application as amended contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows: (i) an enzyme, (ii) functional fragment thereof, (iii) IL-15, (iv) (v) CD40L, (vi) TRAIL; (vii) TRAILrecDRC5, (viii) TRAIL-R2, (ix) TRAIL-R3, (x) TRAIL-

R4, (xi) RANK, (xii) RANK LIGAND, (xiii) OX40, (xiv) OX40 LIGAND, (xv) NKG2D, (xvi) F461811, (xvii) MICA, (xviii) MICB, (xix) NKG2A, (xx) NKG2B, (xxi) NKG2C, (xxii) NKG2E, (xxiii) NKG2F, (xiv) CD30, (xxv) CD153 (CD30L), (xxvi) Fos, (xvii) cjun, (xviii) Sp-1, (xxix) Ap1, (xxx) Ap-2, (xxxi) p38, (xxxii) p65Rel, (xxxiii) MyD88, (xxxiv) IRAK, (xxxv) TRAF6, (xxxvi) Ikb, (xxxvii) NIK, (xxxviii) SAP K, (xxxix) SAP1, (xl) JNK2, (xli) JNK1B2, (xlii) JNK1B1, (xliii) JNK2B2, (xliv) JNK2B1, (xlv) JNK1A2, (xli) JNK2A1, (xlvii) JNK3A1, (xlviii) JNK3A2, (xlix) NF-kappa-B2, (l) p49 splice form, (li) NF-kappa-B2, (lii) p100 splice form, (liii) NF-kappa-B2, (liv) p105 splice form, (lv) NF-kappa-B 50K chain precursor, (lvi) NFkB p50, (lvii) human IL-1 a, (lviii) human IL-2, (lix) human IL-4, (lx) murine IL-4, (lxi) human IL-5, (lxii) human IL-10, (lxiii) human IL-15, (lxiv) human IL-18, (lxv) human TNF-a, (lxvi) human TNF-P, (lxvii) human interleukin 12, (lxviii) MadCAM-1, (lxix) NGF IL- 7, (lxx) VEGF, (lxxi) TNF-R, (lxxii) Fas, (lxxiii) CD40L, (lxxiv) IL-4, (lxxv) CSF, (lxxvi) G-CSF, (lxxvii) GM-CSF, (lxxviii) M-CSF, (lxxix) LFA-3, (lxxx) ICAM-3, (lxxxi) ICAM- 2, (lxxxii) ICAM-1, (lxxxiii) PECAM, (lxxxiv) P150.95, (lxxxv) Mac-1, LFA-1, (lxxxvi) CD34, (lxxxvii) RANTES, (lxxxviii) IL-8, (lxxxix) MIP-1a, (xc) E-selectin, (xci) CD2, (xcii) MCP-1, (xciii) L-selectin, (xciv) P-selectin, (xcv) FLT, (xcvi) Apo-1, (xcvii) Fas, (xcviii) TNFR-1, (xcix) p55, (c) WSL-1, (ci) DR3, (cii) TRAMP, (ciii) Apo-3, (civ) AIR, (cv) LARD, (cvi) NGF, (cvii) DR4 (TRAIL), (cviii) DR5, (cix) KILLER, (cx) TRAIL-R2, (cxii) TRICK2, (cxiii) DR6, (cxiii) ICE, (cxiv) VLA-1, and (cxv) CD86 (B7.2) (claim 77). Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. These species are patentably distinct because they are different proteins encoded by different genes and have different biological functions. The reply must also identify

the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

It is noted that Applicant's response to the election of species for (II) (for claim 77) must be consistent with Applicant's response to the election of species for (I) (for claim 1).

2. Applicant's claims encompass multiple inventions and do not have a special technical feature which link the inventions one to the other, and lack unity of invention. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the

inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 (a) of the other invention.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication from the examiner should be directed to Wu-Cheng Winston Shen whose telephone number is (571) 272-3157 and Fax number is 571-273-3157. The examiner can normally be reached on Monday through Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the supervisory patent examiner, Peter Paras, Jr. can be reached on (571) 272-4517. The fax number for TC 1600 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you

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would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Wu-Cheng Winston Shen/

Patent Examiner

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